CHARGE: 502(f)(1)—when shipped, the labeling (syringe) failed to bear adequate directions for use of the article as a means of self-administration of insulin; and 502(j)—the article was dangerous to health when used according to the dosage scales inscribed on its label.

DISPOSITION: 6–19–61. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6662. Penicillin G potassium tablets. (F.D.C. No. 45896. S. Nos. 83–301/23 R.)

QUANTITY: 578 100-tablet btls. of 50,000 unit *penicillin G potassium tablets* and various drums, cartons and bottles of 50,000, 100,000, 200,000, 250,000, 400,000, and 500,000 unit tablets of penicillin G potassium, totaling 3,369,913 tablets in all, at New York, N.Y., in possession of Pure Laboratories, Inc.

SHIPPED: During 1960 and 1961, from various manufacturers in the State of New York.

RESULTS OF INVESTIGATION: The tablets were repacked by the dealer from *penicillin G potassium tablets* received from various manufacturers who manufactured the tablets from penicillin powder received in interstate commerce.

LIBELED: 5–22–61, S. Dist. N.Y.

CHARGE: 502(l)—while held for sale, the article purported to be a drug composed wholly or in part of penicillin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 6–27–61. Consent—claimed by Pure Laboratories, Inc., and released to be brought into compliance with the law.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6663. Amphetamine sulfate tablets and dextro-amphetamine sulfate tablets. (F.D.C. No. 46116. S. Nos. 31–132/6 R.)

QUANTITY: 2 50,000-tablet drums, 1 btl. of 1,498 tablets, 1 btl. of 2,497 tablets, and 1 can of 6,445 tablets of amphetamine sulfate; 1 btl. of 365 tablets of dextro-amphetamine sulfate, at Mobile, Ala.

SHIPPED: Prior to 7–10–61, from Woodside, Long Island, N.Y., and thereafter transported from Moss Point, Miss., to Mobile, Ala., by Jonathan Mead.

LIBELED: 7–17–61, S. Dist. Ala.

CHARGE: 502(f)(1)—while held for sale by Jonathan Mead, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were prescription drugs which were not and would not be lawfully used nor lawfully dispensed by a practitioner licensed by law to administer such drugs in the course of his professional practice.

DISPOSITION: 8–16–61. Default—destruction.

6664. Sea brine. (F.D.C. No. 45845. S. No. 54–441 R.)

QUANTITY: 8 cases of 24 8-oz. btls. each at Minneapolis, Minn.

SHIPPED: 1–18–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

*See also No. 6661.

LABEL IN PART: (Btl.) "100% Pure Atlantic Ocean Water * * * Sea Brine for Better Health * * * Processed and Distributed by the Florida Sea Brine Laboratries, Inc., P.O. Box 1733, Lakeland, Florida."

LIBELED: 6–28–61, Dist. Minn.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective to promote health; and 502(f)(1)—the label failed to bear adequate directions for use since it did not state the condition or conditions for which the article was intended.

DISPOSITION: 8–10–61. Default—destruction.

6665. Sea brine. (F.D.C. No. 45811. S. No. 20–249 R.)

QUANTITY: 20 cases of 12 8-oz. btls. at Saginaw, Mich.

SHIPPED: 5–2–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

LABEL IN PART: (Btl.) "Sea Brine * * * Concentrated Natural Sea Water * * * Condimize your Foods and Fruit Juices with Natures own 44 Chemicals of the Sea * * * Concentrated and Bottled by Florida Sea Brine Laboratories, Inc., P.O. Drawer 2435, Lakeland, Florida."

LIBELED: 5–25–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was a complete and balanced salt, supplying chemicals, found only in sea water, which are important to good health and which have therapeutic value; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, since the label did not state the condition or conditions for which it was intended.

DISPOSITION: 7–24–61. Default—destruction.

6666. Lix-Pain liniment. (F.D.C. No. 45938. S. No. 79–280 R.)

QUANTITY: 12 6-oz. btls. and 15 1-oz. btls. at Washington, D.C., in possession of James L. Guess.

SHIPPED: 2–15–61, from Kinston, N.C., by Oglesby Chemical Co.

LABEL IN PART: "Lix-Pain * * * Cream Liniment * * * Active Ingredients. Ammonium Carbonate, Camphor, Turpentine, Thyme, Lanolin. Caution: * * * Manufactured by Oglesby Chemical Company Kinston, North Carolina."

ACCOMPANYING LABELING: Circulars entitled "What a Few of the Thousands of Users Say About: Lix-Pain" and bearing the mail-order address of the dealer.

LIBELED: 6–6–61, Dist. Columbia.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for swollen joints, swollen glands, arthritis, neuritis, neuralgia, sinusitis, headache, bruises, sprains, minor burns, cramps, toothache, callouses, corns, and bunions; and 502(f)(2)—the labeling failed to warn that the article should be kept out of the reach of children; that use of the article should be discontinued if excessive skin irritation occurs; that for minor arthritis and rheumatic pains the article should not be used by children under 12 years of age and if pain persists for more than 10 days, or redness is present, a physician should be consulted immediately.

DISPOSITION: 7–26–61. Default—destruction.